

FINAL REPORT

LEGISLATIVE COUNCIL INTERIM COMMITTEE

**CERVICAL CANCER ELIMINATION
2005**

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INTERIM COMMITTEE
SCR110 (2005)**

Members

Senator Joyce Broadsword, Co-chair
Senator Kate Kelly

Representative Bob Ring, Co-chair
Representative Donna Pence

Staff: Maureen Ingram and Charmi Arregui

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FINAL REPORT

Charge

The Legislative Council's Interim Committee on Cervical Cancer Elimination was authorized by Senate Concurrent Resolution No. 110, 2005, which directed the committee to study the prevalence of cervical cancer and human papillomavirus in women in the state of Idaho and to evaluate the current methods of public education and access to regular cancer screening and options for increasing screening accuracy. The committee was further directed to:

1. Identify pockets of need;
2. Identify priority therapies and preventive medicines which are effective in preventing and controlling the risk of cervical cancer;
3. Report its findings of the causes and nature of cervical cancer, personal risk factors, the value of early detection and prevention, options for testing, new technologies, treatment costs, medical care reimbursement issues and physician education; and
4. Report its findings and recommendations, including any proposed legislation, to the Second Regular Session of the Fifty-eighth Idaho Legislature.

Meetings

The committee held two meetings in Boise on August 9 and October 11, 2005. The minutes of the two meetings are available on the Internet at the Legislature's home page, "www.legislature.idaho.gov/" under Prior Sessions, 2005 Session, 2005 Interim Committees, Cervical Cancer Elimination Interim Committee.

Human Papillomavirus (HPV) and Cervical Cancer

According to testimony from well-qualified physicians, HPV is a sexually-transmitted skin virus which attacks the cervix. Cervical cancer develops in the lining of the cervix; normal cervical cells may gradually undergo changes to become precancerous and then cancerous. Cervical intraepithelial neoplasia, or CIN, is the term used to describe these abnormal changes. CIN is classified according to the degree of cell abnormality. The higher the CIN number, the greater the abnormality.

Sometimes HPV will spontaneously regress to normal, but some of these viral infections progress to pre-cancerous lesions called dysplasia. Two-thirds of women with low-grade dysplasia eventually overcome the virus on their own, while about 14% will progress to cervical cancer. Cervical cancer is unique in that it is a slow-developing cancer taking about six to seven years in most patients, unless the patient has a poor immune system, in which case it will progress faster.

Cervical cancer, if caught at an early stage, has a very high survival rate, but if it is first detected at a late stage, survival rates are very poor.

Testing and Technologies

The standard test for assessing the condition of the cervix is a Pap smear. An abnormal Pap smear does not necessarily indicate a woman's condition will turn into cervical cancer, but can

indicate the presence of an HPV infection. With regular Pap smears and appropriate follow-up, cervical cancer is completely treatable and preventable. Pap smears are therefore very important as a means of early detection. Pap smears, however, will accurately identify only approximately half of the women who have abnormal cells, or put in another way, Pap smears have about a 40% false negative rate; some dysplasia may exist but might not be detected. With yearly Pap tests, the chances of detecting a true abnormality are greatly increased. The strength of Pap smear testing lies in its repeated use.

When additional testing is indicated, a colposcopy can be performed. This procedure is done with a sophisticated instrument designed to facilitate visual inspection of the vagina and cervix. A biopsy is taken and the findings are interpreted by a pathologist. A pregnant CIN 1 patient, or a patient with high risk HPV, is generally given a colposcopy.

A more sensitive test, ThinPrep, can be administered instead of a Pap smear. Its increased sensitivity will detect more low-grade CIN conditions and therefore has a lower rate of false negatives, but a ThinPrep is not as specific, increasing the potential for more false positives. A ThinPrep test can be more costly than a standard Pap smear, but when appropriately used, the cost can be offset by the savings in following up a positive Pap smear with a colposcopy. ThinPreps can also be used as an alternative to a colposcopy. In general, ThinPreps result in lower operational costs in total patient care by reducing the necessity for repeat patient visits, fewer unsatisfactory tests, fewer less-than-optimal Pap smears, and fewer patients needing a colposcopy and direct biopsy.

ThinPreps became available in 1996. Since then, two other liquid-based cytology products have been approved by FDA for the Pap smear screening process.

Therapies

Early testing and screening are the most effective methods for the control and treatment of cervical cancer. Early detection and treatment are key, and therefore the emphasis continues to be on prevention. Pap smears work best in situations where the test is repeated. If it is repeated three years in a row, almost all women with abnormal cells will be diagnosed.

If testing indicates a pre-cancerous condition, several options are available to treat the portion of the cervix that is abnormal. The area may be frozen; minor surgery can be performed; or a more advanced surgery may be done to excise a cone-shaped portion higher in the cervix. For cervical cancer, an advanced cancer surgery may be indicated.

According to Merck & Co.'s announcement in October, 2005, their short-term studies have shown its experimental vaccine to be "100 percent effective in combating the virus that causes" cervical cancer. The vaccine works to protect women against the two types of sexually-transmitted HPV's that cause most cases of cervical cancer. If the federal Food and Drug Administration approves the vaccine in the near future, the vaccine may be available by mid-2006. Potentially, everyone is at risk for HPV. To work, the vaccine should be administered to both males and females, ideally before they become sexually active. Even after activity has begun,

women should be protected from the exposure men present.

Risk Factors and At-Risk Populations

When a young girl reaches puberty, an area of the cervix becomes cellularly active and it is during this time those cells are especially susceptible to HPV. Simply delaying sexual activity for at least a year during this time can dramatically decrease the incidence of HPV. Because HPV is a skin virus, standard precautions for sexually-transmitted diseases are not effective in its prevention.

The at-risk population includes teenaged young women and women with sexual abuse histories; early onset first intercourse; teens with multiple sex partners; women with unstable relationships and multiple sex partners; women who have immune deficiencies such as those with HIV or who have had transplants; women with poor access to testing and screening; smoking; substance abuse; and not being tested annually as a preventive measure due to financial and other social barriers.

With cervical cancer, the risk factors cause the disease to progress rapidly, especially in women whose immune systems are compromised, as in those who smoke and engage in substance abuse. Infertility in later life is highly associated with having contracted a sexually-transmitted disease as chlamydia, herpes, HPV and others, earlier in life, and is compounded by all risk factors.

Prevalence

In Idaho, HPV affects 60-75% of all adults, the same percentage of incidence as HPV affects the United States, and most of these infections are never detected or even noticed.

Cervical cancer statistics show that the disease is not as big a problem in Idaho as it is in other states; it ranks fourteenth for cause of death among cancers in Idaho. The five-year survival rate for cervical cancer in Idaho was 60% during the years 1994-2003. With the advent of Pap smears in 1950, the cervical cancer rate decreased by 60%, but in the last ten years, the rate has statistically remained the same. In 2003, forty-two new cases of cervical cancer were diagnosed: twenty-five cases were curable with simple treatment, and there were fourteen deaths. Data on the incidence of cervical cancer in Idaho by health districts is available.

Men are the major carriers of HPV, but they do not get cancer from HPV. Men, however, can contract genital warts from one strain of the virus. They carry the virus and transmit it to women. HPV is very common; cervical cancer is not. Women ages 20-30 years have the highest rate of CIN, and CIN 1 is common in young women. Approximately sixty percent of CIN 1 lesions regress within six years, unlike the 10% to 20% of CIN 3 conditions which progress to invasive cancer.

Nationally, more than 10,000 women develop cervical cancer annually, more than half of these never had a Pap smear, and over 3,000 die. Even so, the United States has a very low rate of cervical cancer which is generally attributed to an effective, well-established Pap screening

process. In contrast, Mexico has the highest incidence of cervical cancer in the world. Cervical cancer is still the leading cause of cancer death among women in parts of the world where Pap tests are either not available or are not readily available.

Costs and Funding

According to Idaho Medicaid statistics, for state fiscal years 2001 through 2005, \$13,610,690 was paid on claims for cervical cancers that were malignant neoplasms, carcinoma *in situ*, and dysplasia. The distribution of the dollars paid is significant. More claims are paid in the lower cost categories, but for just two claims for malignant neoplasm, the state paid over \$1 million. Thousands of Pap smears could be funded for the cost of treating just one cancer, making early detection key to controlling costs as well as protecting public health.

Under Idaho's Breast and Cervical Cancer Medicaid program (BBC), expenditures for fiscal year 2005 were \$2,076,200: eighty percent was paid from federal funds and twenty percent with state funds. This program does not allow for treatment of any woman over the age of 65.

Women's Health Check (WHC) is funded by the Centers for Disease Control and Prevention (CDC) and is highly-regulated with respect to the population it serves as well as the specific tests that can be given. The Idaho WHC is at capacity with the level of federal funding it receives, yet it covers less than 15% of the eligible population. WHC also sponsors the Idaho Care Line, a telephone access line to the Department of Health and Welfare where citizens can receive referrals to local care providers and help with other health issues.

Seven health districts operate family planning clinics in 40 of Idaho's 44 counties. Funding for these clinics this year was \$2.4 million in contract funds received from federal Title X and Maternal Child Health Block Grant funds. District health departments supplement these clinic services with their general funds and local taxes. The majority of these funds, however, must be utilized for family planning services, with cervical cancer screening being only part of their total program. In 2004, family planning clinics in Idaho performed 17,833 Pap smears as well as completing the needed contact and follow-up for both normal and abnormal test results. A combination of traditional as well as ThinPrep technology was utilized for these tests. With a special discount from IDX lab, the cost for each test ranged between \$9-\$14.

The public health system is close to capacity from a financial standpoint. The challenge is to be reimbursed for testing. Some partnerships between public and private clinics have been formed. In exchange for screening services, they receive extra money to collect data and information.

The Cancer Data Registry is currently funded primarily by a grant from the Centers for Disease Control and Prevention, and from a small portion of the Idaho cigarette tax.

Medicare and Medicaid laws specify that the laboratory performing a screening test must bill for the test, and the reimbursement rate is set annually by Medicaid. Pap smear reimbursement to laboratories is approximately \$14 per smear. ThinPreps are reimbursed by Medicare at the rate

of \$25, and for an advanced HPV/DNA, \$60.

Community health centers provide formal and informal referral arrangements with community hospitals, other medical providers, specialists, and social service agencies. They also maintain partnerships with many other organizations and institutions including Idaho universities, faith organizations, foundations, the American Cancer Society, local health districts and the Department of Health and Welfare.

Education

Education and awareness are the keys to successfully eliminating cervical cancer in the future. Preventing the spread of the virus is preferable to dealing with the consequences of HPV and cervical cancer. Because of the lag time between exposure to HPV and the occurrence of cervical cancer, it is more difficult to educate on the connection between the two.

With increased sexual activity occurring at a much younger age, and with increased methamphetamine use, it is as critical to provide education on the importance of annual Pap smears as it is to provide education regarding abstinence. Young people should be informed about sexually-transmitted diseases (STD's) and the long-term effects of their behaviors. It is also important to educate people that birth control pills will not protect them from STD's, including HPV.

Idaho's population is increasing from in-migration of diverse groups, many of which are bringing in new, more virulent strains of STD's. Often these immigrants are coming from areas where there is little education about the necessity for Pap testing.

Currently, many doctors take the opportunity when prescribing birth control pills to educate about STD's, HPV, the need for annual Pap smears, and the importance of following a recommended treatment plan when there is an abnormal Pap smear.

Beginning in 1996, Women's Health Check partnered with the Cancer Data Registry, the American Cancer Society and others to combine their efforts to better educate, without duplication, and to conduct outreach programs. As of June 30, 2005, Idaho became a comprehensive cancer planning state, meaning that a group will have the responsibility at the state level to look at testing, screening and management of all cancers to ensure there is no duplication or unnecessary overlap.

The state Department of Health and Welfare is sponsoring radio and print advertisements targeted at the 18-24 year-old age group to make the connection between contracting an STD and the long-term risks associated with it. To some, the ads are of a very graphic nature and have drawn negative reactions from some groups. However, a recent survey in the north Idaho health district showed that 30% of the women using the family planning clinic were presenting with HPV infections. It is becoming almost an indigenous disease, emphasizing the need to educate on prevention of HPV. The department spent \$200,000 on these ads last year and will spend another \$200,000 this year. The effectiveness of the ads will be evaluated and reported, and if they are having the desired effect, additional moneys may be requested from the Legislature.

Schools are generally reluctant to give information about STD's to their students; church groups have been the most responsive.

Community health centers are in communities that otherwise would not have accessible health care, have staff that are culturally and linguistically competent, and incorporate outreach, health education and case management in the scope of their services.

Barriers to Treatment and Gaps in Service

Barriers to treatment of HPV and cervical cancer, and gaps in service are logistical access including transportation, medical management, fear, denial and cultural barriers, and economic factors. Lack of access to physicians for screening, testing and treatment is a predominant problem in Idaho. There are four counties which have no physician at all, other counties have no access to an obstetrician/gynecologist, and there is only one gynecological oncologist in the state. Many counties in Idaho do not have a physician who is trained in techniques used to treat women with abnormal Pap smears, making it necessary to send rural patients to Boise, Twin Falls, Idaho Falls, Pocatello, Lewiston or Coeur d'Alene. Much of the care in rural areas is provided by nurse practitioners, physician assistants and family practice physicians.

In Idaho, there is a significant substance abuse problem and a significant lack of access to mental health facilities. People in these situations make poor choices regarding sexual behavior, engage in activities that compromise their immune systems putting them at greater risk for HPV, and are less likely to seek preventive treatment.

There are also social and cultural barriers. Women's Health Check (WHC) expends great effort to find eligible women, ages 50 through 64 years of age, who have never been screened or who have not had annual screenings. Even if they are identified, and even if the screening is free, often it is a problem getting such women to a facility. There is a higher rate of cervical cancer among Idaho Hispanic and Latino women who tend to be reluctant to be checked due to cultural factors. WHC does not have funds for all diagnostic tests, creating a gap in treatment services for the uninsured population who are under 49 years of age, especially the 30-50 years of age group, within the public health care system. WHC is not comprehensive enough to meet all the needs, and it was noted that ways to complement their program would be welcomed.

Limited finances, inability to qualify for Medicaid, or lack of insurance are barriers to testing and treatment. The lack of access to medical care by poorer members of the population has remained constant. Rather than seeking precautionary tests, these women wait until there is a problem and they are the ones who are most likely to have late-stage cancer. Awareness campaigns regarding HPV and cervical cancer would help to improve motivation for testing and treatment throughout the state.

With regard to public health districts, while they are providing extensive Pap smear testing as well as teaching and educating about risk factors associated with cervical cancer, a significant gap exists in their ability to provide referrals for diagnostics and treatment of precancerous lesions.

Presenters

1. Dr. Lee Parsons, Chairman, Idaho Section, American College of Obstetricians and Gynecologists on *“Medical Basics of Cervical Cancer”*
2. Dr. Patrice Burgess, President, Idaho Medical Association and faculty member at the Family Medicine Residency of Idaho on *“Cervical Cancer in Family Practice”*
3. Dr. Leigh Morse, Family Practice Medical Center of Idaho on *“Cervical Cancer in the Family Practice Residency Program”*
4. Dr. Michael Myhre, founder and owner of IDX Pathology; President-elect of Ada Canyon Medical Society; and Trustee District 4 of the Idaho Medical Association on *“The Pathology of Cervical Cancer”*
5. Dr. Jerry Perez, program administrator for gynecology oncology, St. Luke’s Regional Medical Center and St. Alphonsus Regional Medical Center on *“Cervical Cancer and the Oncologist”*
6. Mr. Chris Johnson, epidemiologist, Cancer Data Registry of Idaho on *“Idaho Cervical Cancer Statistics”*
7. Minnie Inzer Muniz, Women’s Health Check, Division of Health, Idaho Department of Health and Welfare on *“Public Health Screening, Diagnosis and Treatment in Idaho: CDC and Medicaid Funding”*
8. Ms. Brenda Vanden Beld, Acting Manager, Reproductive Health, Department of Health and Welfare on *“The Role of Public Health Districts in Cervical Cancer”*
9. Mr. Bill Foxcroft, Executive Director, and Susan Ault, Clinical Services Director, Idaho Primary Care Association on *“The Role of Community Health Centers in Cervical Cancer”*
10. Mr. Tom Rosenthal, Research Analyst Supervisor for the Division of Medicaid, Department of Health and Welfare on *“Medicaid Payments”*

Supplementary Presenters and Information

1. Dr. Christine Hahn, State Epidemiologist, Department of Health and Welfare
2. Mr. Richard Schultz, Administrator, Division of Health, Department of Health and Welfare
3. Mr. Dan Heincy, R.P.H., U.S. Human Health, Merck & Co.
4. Mr. R. Scott Burns, Health Policy, Merck Vaccine Division
5. Dr. Alan Shaw, Executive Director, Virus and Cell Biology, Merck Research
6. Ms. Jean Scepka, Clinical Coordinator, Women’s Health Check, Department of Health and Welfare
7. Mr. Brad Hoaglund, American Cancer Society
8. Centers for Disease Control and Prevention national webcast: *“HPV and Cervical Cancer: An Update on Prevention Strategies.”*
9. *“Annual Report of the Cancer Data Registry of Idaho, Cancer in Idaho-2003,”* dated April, 2005.
10. *“ACOG Practice Bulletin,”* Number 45, August, 2003.

Findings and Recommendations

1. Physician education. Rural areas of Idaho are limited in their access to physicians, and the medical care that is available tends to be broad-based. Often physicians are not trained in techniques used to treat women with abnormal Pap smears. According to testimony, physicians need to keep their skills updated on the more sophisticated procedures, especially with regard to interpretations and treatments. There are continual changes making it necessary to constantly update technical skills.
2. Education of at-risk populations. Building awareness of the critical need for annual Pap smear testing is important to the prevention of cervical cancer. Colleges and universities should be contacted to participate in advertisement campaigns and other programs to educate on the need for good health, safe behaviors, and annual Pap smear testing for women. Public school districts should be encouraged to provide education where appropriate and within the curriculum and guidelines under which each district operates. The Department of Health and Welfare is supported in its advertising campaigns as a proactive approach to education and outreach.
3. Access available funds. Basic preventive services are of particular importance to low-income, uninsured women who are generally without access to health care but are at the greatest risk for HPV and cervical cancer. Public providers of health care are encouraged to continue their efforts to explore all potential sources of federal and other funding in order to provide access to screening for this segment of the population.
4. Complementary committees. The germane committees of the Legislature, the Health Care Task Force and other similar groups with authority to continue their investigations, are encouraged to seek increased health care access for the at-risk population.
5. Reporting to the legislature. The Department of Health and Welfare, in collaboration with the American Academy of Pediatrics, the American Academy of Family Physicians, the American Cancer Society and the American College of Obstetricians and Gynecologists, should report new cervical cancer treatments, preventive technologies, and recommendations to the germane committees and legislative leadership of the Legislature of the state of Idaho on an annual basis through the 2008 legislative session.